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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,226	01/27/2006	Gilad Lavi	S2082/20003	3732

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
05/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,226	LAVI ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevallier et al. FR 2616221). Chevallier discloses an injection device (Figs. 8 and 9) comprising: a housing (104) having a proximate end (near reference number 110) and a distal end (near 102), the distal end having an opening therein (opening 126); a cartridge barrel (116) within the housing, the cartridge barrel having proximate and distal ends (115 and 118a, respectively); a needle cannula (180) fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper within the cartridge barrel (the stopper portion is the rectangular portion fixed to 117, the stopper portion being located above the 190 closest to 117); a driver coupled to the stopper (the driver is composed of the assembly that includes 117, 140, 120, 106, 160, etc.); a shield (166) coupled to the housing and slidable between a retracted and an extended position (Fig. 9 discloses the retracted position and Fig. 8 discloses the extended position. 166 is disclosed as sliding relative to the housing); shield driver means (123) activatable to urge the shield from the retracted position to the extended position; and sensor means (the combination of 165 and 160 comprise the

sensor means) forming a portion of said driver (160 is as described above a portion of the driver) and in slidable contact with an exterior surface of said cartridge barrel (Fig. 9 discloses that 165 (being the elongate piece that 160 bears against in Fig. 9 and the piece that 160 caps in Fig. 8) slides along the housing) the sensor means arranged to detect an end profile of the barrel and to automatically trigger activation of the shield driver means upon detection (Fig. 9 discloses that the sensor means 165 slides along the barrel, while 160 forces 165 against the barrel, and when 165 has slid beyond the end of the barrel, 160 senses that 165 is no longer in contact with the barrel and 160 forces 165 downwards and automatically activates/triggers the activation of the shield driver means as seen in Fig. 8 and the shield is released to extend around the needle).

In reference to claim 2, Chevallier discloses that the shield driver means comprises a coil spring (123) within which the cartridge barrel is located.

In reference to claim 3, Chevallier discloses that the shield driver means comprises a release mechanism for fixing the spring relative to the driver in a compressed state, the release mechanism being actuable by said sensor means to release the spring (170).

In reference to claim 4, Chevallier discloses that the driver is arranged to be manually pushed through the housing, the driver carrying the shield driver means to a shield activation point (manually activated by 155).

In reference to claim 5, Chevallier discloses that the coil spring is fixed at its proximal end to the driver, and the spring release mechanism fixes the spring to the driver at its distal end (at 166).

In reference to claim 6, Chevallier discloses that the shield driver means additionally provides a driving force for said driver (123 is connected to 166 which is connected to the driver).

In reference to claim 7, Chevallier discloses that the coil spring is fixed at its proximal end to the housing and the spring release mechanism fixes the spring to the driver at its distal end (Fig. 8).

In reference to claim 8, Chevallier discloses that the sensor means comprises one or more deformable arms attached or formed integrally with the driver (160 is being interpreted as the deformable arm which is attached to the driver).

In reference to claim 9, Chevallier discloses that each arm is biased against the exterior surface of the cartridge barrel and arranged to follow the surface profile of the barrel (Figs. 8 and 9).

In reference to claim 10, Chevallier discloses that the release mechanism comprises a catch provided on a radially outer surface of each deformable arm (the catch portion of 160).

In reference to claim 11, Chevallier discloses that the driver and said sensor means are a single molded plastic element (Figs. 8 and 9).

Claims 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevallier et al. FR 2616221). Chevallier discloses an injection device (Figs. 8 and 9) comprising: a cartridge barrel (116), said barrel arranged to contain a stopper and fluid

therein (the stopper portion is the rectangular portion fixed to 117, the stopper portion being located above the 190 closest to 117) and wherein said barrel has a second open end (near 115) and a second end having a radial flange (119) adjacent to the second end; a needle cannula (118) having a sharp distal end (near 118b) and a second open end (near 118a), the fluid being in communication with said needle second end; a housing (104) surrounding said barrel, said housing having a distal open end (126) adjacent the needle and a proximate end having a flange (122) receiving the radial flange of the barrel; a shield (166) releasably retained by the housing (retained by the upward extending part of 166), said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (Fig. 9); a driver (the driver is composed of the assembly that includes 117, 140, 120, 106, 160, etc.), said driver positioned partially within said housing, said driver equipped with at least one deformable side arm sensing the end of the barrel (160 is being interpreted as the deformable side arm, which senses the end of the barrel when portion 165 is no longer in contact with the barrel (it reaches the end of the barrel) and 160 no longer bears against the side of 165), said driver slidingly located within said housing for moving the stopper forward (Figs. 8 and 9 disclose that the driver assembly slides within the housing in order to move the stopper forward); and a biasing spring (123), said biasing spring further adapted to bias the shield to automatically cover the needle after said driver detects the end of the barrel (Fig. 9 discloses that the sensor means 165 slides along the barrel, while 160 forces 165 against the barrel, and when 165 has slid beyond the end of the barrel, 160 senses that 165 is no longer in contact with the barrel

and 160 forces 165 downwards and automatically activates/triggers the activation of the shield driver means as seen in Fig. 8 and the shield is released to extend around the needle).

In reference to claim 13, Chevallier discloses that the biasing spring is carried by the driver and is released to bias the shield when the end of the barrel is reached (Figs. 8 and 9).

In reference to claim 14, Chevalier discloses that the driver has two sensor elements to detect the end of the barrel (160 is the detecting element).

In reference to claim 15, Chevallier discloses that the housing and shield are equipped with latches (Figs. 8 and 9).

In reference to claim 16, Chevallier discloses that the latches prevent premature release of the shield (Figs. 8 and 9).

In reference to claim 17, Chevallier discloses that the latches retain the shield in a needle shielded position (Fig. 8).

In reference to claim 18, Chevallier discloses that the driver is deformable during assembly (Figs. 8 and 9).

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767